

### REMARKS

**Interview Summary:** Applicants' agent thanks the Examiner for the telephone interview graciously provided on November 6, 2009, in which the application in general was discussed. The MPEP suggests that, to be complete, an interview summary—even when one is already received from the examiner—must address the following issues. Applicants' summary follows each category.

(A) a brief description of the nature of any exhibit shown or any demonstration conducted;-----none

(B) identification of the claims discussed;-----NA

(C) identification of specific prior art discussed; ----- NA

(D) identification of the principal proposed amendments of a substantive nature discussed, unless there are already described on the Interview Summary form completed by the examiner; ----- Supportive information in the specification was discussed in light of how the allowable subject matter of the claims could be expanded from that suggested in Office Action. Addition of experimental data to broaden allowable claim coverage was also discussed.

(E) the general thrust of the principal arguments of the applicant and the examiner should also be identified; ----- no arguments were made

(F) a general indication of any other pertinent matters discussed;-----none

(G) if appropriate, the general results or outcome of the interview; -----Applicants' agent agreed to amend the claims, submit supportive experimental data and point out in specification the support for the scope of amended claims.

#### **Office Action Response:**

Claims 1-44 were presented at the time of entry into the national phase under 35 USC 371. By preliminary amendment accompanying the filing, claims 1-44 were canceled and new claims 45-63 were entered. In response to a Restriction Requirement, claims 45-62 were elected; claim 63 is withdrawn from consideration. In response to an election of species for examination, Applicants elected the species of claim 46 in which R is hydrogen for the treatment of bacterial infection. This species is read upon by claims 45-48, 54-56 and 58-62. In the previous

communication, claim 45 was amended. In the interest of moving this application toward allowance, claim 63 is canceled; however, Applicants reserve the right to pursue this claim, and any other canceled claims, in a divisional application. In this communication, claims 45-63 are canceled and new claims 64-75 are added. No new matter has been added, as the subject matter of new claims 64-75 corresponds to that of canceled claims 45-63.

It is believed that the Examiner's rejections are overcome with the following arguments, so no additional claims are currently canceled or withdrawn. Therefore, the claims currently pending are 64-75.

Applicants thank the Examiner for her withdrawal of the § 103 and § 112, first paragraph, rejections of the previous Office Action.

**Rejection of claims under 35 U.S.C § 112**

Claims 45-48 and 54-62 are rejected under section 112, first paragraph as lacking enablement for treatment of diseases/conditions other than breast cancer and HSV-1 infection. Applicants thank the Examiner for her guidance in the telephone interview regarding those conditions and diseases for which there is support, especially as it relates to bacterial and viral infections.

New claim 64 corresponds to previous claim 45, but has limited those diseases and conditions to be treated in order to advance prosecution to allowance. In the Office Action, the Examiner indicated that there was support for the treatment of breast cancer. Applicants would also like to point out the support for lung cancer on page 47 of the specification, wherein it is shown that casuarine and 3-epi-causarine both severely limit the spread of metastases in murine lungs when compared to the control. This was pointed out in the telephone interview to the Examiner, who indicated that this should provide enough support for claiming the treatment of lung cancer. Therefore, both lung and breast cancer are now claimed.

Applicants submit a Declaration from Dr. Jonathon Tinsley (submitted as Appendix A) describing various tests that were performed under his supervision using compounds of the instant invention as treatments for various bacterial and viral infections. As is well known, Ebola virus is exceedingly deadly. Ebola virus was tested in mice, with survival as the endpoint. The results showed that treatment with casuarine led to a 20% survival rate in Ebola virus-infected mice. Further, the Examiner pointed out in the Office Action that there is support for HSV-1 treatment in the specification. The compounds of the instant application have shown anti-viral

activity in two different viruses, supporting the claim that these compounds are effective anti-viral treatments. Ebola virus has been added as a choice in claim 72.

The Tinsley Declaration (Appendix A) also details experiments performed using compounds of the instant invention as treatments against various bacteria. These compounds showed compelling evidence of effectiveness as treatments against *Escherichia coli*, *Francisella tularensis* (the causative agent of tularemia) and *Bacillus anthracis* (the causative agent of anthrax). All three of these bacteria were tested in mice, with survival of the mice as the endpoint. As can be seen from the results table, the two compounds of the instant invention tested demonstrated survival rates of 20-80% in the affected mice. These results, coupled with the inhibition of  $\alpha$ -D-glucosidase in yet another bacterial strain (*Bacillus stearothermophilus*) shown in Example 4 of the specification (see results on page 44), demonstrate solid antibacterial activity of the compounds of the instant invention.

### Conclusion

Applicant respectfully asserts that this amendment overcomes the § 112 rejection. The Commissioner is hereby authorized to charge payment of the two-month extension of time fees that are due and any additional fees that may be required, or credit any overpayment of same, to Deposit Account No. 08-1935, Reference No. 3073.054.

Respectfully submitted,



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## APPENDIX A